

MAUDE Adverse Event Report: KERR CORPORATION MAXCEM ELITE CEMENT, DENTAL Page 1 of 3

U.S. Food & Drug Administration

MAUDE Adverse Event Report: KERR CORPORATION MAXCEM ELITE CEMENT, DENTAL

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KERR CORPORATION MAXCEM ELITE CEMENT, DENTAL

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Catalog Number 33872

Event Date 12/16/2011

Event Type Injury Patient Outcome Other, Required Intervention

Manufacturer Narrative

The bruxer crown was re-cemented with a different product without further incident and the patient is doing fine. The product involved in the alleged incident was not returned, therefore, retain samples were evaluated for adhesive strength and were found to meet product specifications. In addition no similar complaints were received with regard to this lot. These investigation results indicate that this incident is an isolated incident that occurred as a result of a user/technique related issue and was not due to a product failure.

Manufacturer Narrative

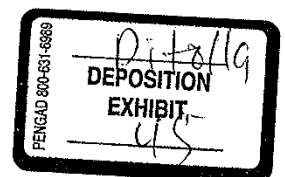
The product involved in the alleged incident was returned and evaluated for adhesive strength, yielding results within specifications.

Event Description

A doctor alleged that two (2) patients experienced the debonding of crowns after placement with maxcem elite clear. This mdr is the second of two (2) reports.

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Brand Name MAXCEM ELITE
 Type of Device CEMENT, DENTAL
 KERR CORPORATION
 Manufacturer (Section F) 1717 West Collins Avenue
 Orange CA 92867
 KERR CORPORATION
 Manufacturer (Section D) 1717 West Collins Avenue
 Orange CA 92867
 KERR CORPORATION
 Manufacturer (Section G) 1717 West Collins Avenue
 Orange CA 92867
 Orlando Tadeo, Jr.
 1717 W Collins Ave
 Manufacturer Contact Orange, CA 92867
 (714) 516 -7419
 Device Event Key 2445512
 MDR Report Key 2424285
 Event Key 2321120
 Report Number 2024312-2012-00021
 Device Sequence Number 1
 Product Code EMA²²
 Report Source Manufacturer
 Source Type Health Professional
 Reporter Occupation DENTIST
 Type of Report Initial, Followup
 Report Date 12/21/2011
 1 Device Was Involved in the Event
 1 Patient Was Involved in the Event
 Date FDA Received 01/20/2012
 Is This An Adverse Event Report? Yes
 Is This A Product Problem Report? No
 Device Operator DENTIST
 Device EXPIRATION Date 08/01/2012


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Device Catalogue Number33872
 Device LOT Number3631284
 Was Device Available For Evaluation?Yes
 Is The Reporter A Health Professional?Yes
 Was The Report Sent To Manufacturer?No
 Date Manufacturer Received12/21/2011
 Was Device Evaluated By Manufacturer?Yes
 Date Device Manufactured04/15/2011
 Is The Device Single Use?No
 Is this a Reprocessed and Reused Single-Use Device?No
 Is the Device an Implant?No
 Is this an Explanted Device?
 Type of Device UsageUnknown

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 10903 New Hampshire Avenue


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